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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,390	12/21/2000	Jens Kossmann	GFB-5 DIV	9564

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EXAMINER

FOX, DAVID T

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 06/19/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/746,390

Applicant(s)

Kossmann et al

Examiner

FOX

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE -3- MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 3/28/02
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 48-49, 51-57, 60-63, 65-69, 73-76, 81, 88-95 is/are pending in the application.
Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 48, 49, 51-57, 60-63, 65-69, 73-76, 81, 88-95 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☒ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☒ received in Application No. (Series Code/Serial Number) 09/045,360
 - ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

Office Action Summary

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Applicant's election without traverse of Group V in Paper No. 7 is acknowledged.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Specifically, the first page of the specification should indicate that parent application Serial No. 09/045,360 filed 19 March 1998, now U.S. Patent 6,207,880, is a continuation of PCT/EP96/04109 filed 16 September 1996.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49, 51-57 and 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 49 is indefinite in its recitation in lines 3-4 of "said second nucleic acid molecule" which lacks antecedent basis in the claims. Dependent claims are included in the rejection.

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 48 and 60 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The DNA or RNA molecules, as claimed, have the same characteristics and utility as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Distintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brogdex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Amending line 1 of the claim 48 to replace "A" with --An isolated--, and amendment of line 1 of claim 60 to insert --isolated-- after "An", would obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 48-49, 51-57, 60-63, 65-69, 73-76, 81 and 88-95 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited the reduction in a glucan phosphorylase protein following plant transformation with an antisense construct comprising an entire gene encoding a native potato granule-bound protein comprising SEQ ID NO:2; does not reasonably provide enablement for claims broadly drawn to any gene from any source or sequence or any fragment of any length which encodes either a granule-bound or soluble protein, for any ribozyme-mediated gene inhibition, or for any other type of non-exemplified protein reduction. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification does not provide any guidance for any modification or derivation of SEQ ID NO:1; for the identification and isolation of any corresponding protein or gene from any other plant source; for the identification or isolation of any fragment or derivative of SEQ ID NO:1 which would retain the ability to encode a functional protein involved in starch metabolism; for the identification or isolation of any soluble protein; for the identification or isolation of any nucleic acid hybridizing to SEQ ID NO:1 or to a gene encoding SEQ ID NO:2 as recited in part (c) of claims 48, 61 and 81, wherein said hybridization could occur under unspecified conditions including moderate or low stringency, and so could encompass a multitude of non-exemplified nucleic acid sequences having a multitude of sequences and functions; or for the modification or derivation of any of a multitude of uncharacterized sequences which hybridize to the exemplified gene as recited in part (e) of claims 48, 61 and 81. In addition, the specification does not provide any guidance for ribozyme-mediated gene inhibition as broadly claimed in claims 49, 63 and dependents; or for any other type of non-exemplified method for the "reduction" of protein expression as broadly claimed in claim 61 and dependents. Furthermore, the specification does not provide any guidance for the evaluation of a multitude of non-exemplified fragments or derivatives of SEQ ID NO:1 in antisense orientation, or a multitude of antisense constructs comprising a multitude of non-exemplified genes from a multitude of non-exemplified sources, for their ability to alter phosphorylase protein production and

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starch accumulation in transformed plant cells, as broadly claimed in parts (c) and (e) of claims 48, 61 and 81 and in claim 62.

The isolation of genes involved in starch accumulation in plants is particularly unpredictable. See Kossmann et al (1985; Progress in Biotechnology, Volume 10), who teach the difficulty inherent in isolating individual starch synthesis enzymes or their corresponding genes (paragraph bridging pages 275 and 276).

In addition, the process of modifying starch accumulation in transgenic plants is particularly unpredictable. See Kossmann et al (1985; Progress in Biotechnology, Volume 10), who teach the lack of influence of antisense potato starch accumulation genes on branching or phosphate content of starch (page 275, third through fifth full paragraphs), and the lack of correlation between reduction of branching enzyme gene activity and branching of starch in transgenic plants (see, e.g., page 277, penultimate paragraph).

See also Sonnewald et al, page 567, Abstract, who teach the lack of correlation between plant transformation with a gene encoding a potato glucan phosphorylase and actual changes in starch accumulation. See also Saint-Pierre et al who teach that the control of potato starch phosphorylase gene expression is poorly understood and involves factors other than rates of transcription (see, e.g., page 1088, column 1, bottom paragraph; page 1091, paragraph bridging the columns; page 1095, page 1095, column 1, bottom paragraph).

Furthermore, non-exemplified means of gene inhibition such as ribozymes have not been demonstrated to effect gene inhibition or phenotypic change *in planta*. See Evans et al, page 344S,

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paragraph bridging columns 1 and 2, who teach that neither cleavage of target RNA nor reduction in the target gene product were observed in plant cells. See also Mazzolini et al, who teach low activity of ribozymes in intact plant cells and negligible reduction of enzyme activity following cell transfection with genes encoding ribozymes specific for the target enzyme, even when the ribozyme genes themselves were highly expressed (see, e.g., page 716, column 1, first full paragraph; page 722, bottom paragraph of each column; page 723, column 1; page 726, bottom paragraph of each column; page 728, column 2, first full paragraph; page 729, first full paragraph of column 1, first paragraph of column 2). See also Kull et al, page 69, Abstract, who teach that ribozymes corresponding to potato starch synthesis genes did not alter starch accumulation in potato plants transformed therewith.

See also Newman et al and appended Sequence Search submitted in parent application Serial No. 09/045,360, where it was taught that fragments of the exemplified genes are found in the *Arabidopsis* gene of unidentified function taught by Newman et al, wherein it is unlikely that plant transformation with such a gene would have any effect on starch accumulation.

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to identify and isolate a multitude of genes from a multitude of non-exemplified plants, to identify and isolate a multitude of non-exemplified soluble proteins, to identify and isolate a multitude of non-exemplified fragments or sequence variants of the exemplified genes, to isolate and characterize a multitude of sequences which would hybridize to the exemplified genes under conditions of low or moderate stringency, or to isolate and characterize a multitude of fragments or derivatives of the hybridizing nucleic acids of

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any length or sequence. Furthermore, undue experimentation would have been required to evaluate the ability of any of the multitude of non-exemplified sequences mentioned above to confer phenotypic change or changes in starch accumulation to plants transformed with antisense constructs containing them. Finally, undue experimentation would have been required by one skilled in the art to evaluate and obtain successful gene inhibition and starch alteration using non-exemplified means such as ribozymes.

See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 USPQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein.

Claims 48-49, 51-57, 60-63, 65-69, 73-76, 81 and 88-95 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a multitude of non-exemplified sequences and sequence fragments from a multitude of sources, as stated above, and their use. In contrast, the specification lacks any guidance for the obtention or characterization of any of these fragments, derivatives, or other non-exemplified sequences, as stated above. The specification also lacks guidance for the obtention or characterization of any ribozyme-encoding sequence or any ribozyme transcribed therefrom.

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Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the invention. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the broadly claimed invention at the time it was made.

See Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ 2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

See University of California v. Eli Lilly and Co., 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 48, 51-54, 60-62, 68, 69, 73-76, 81 and 88-95 are rejected under 35 U.S.C. 102(b) as being anticipated by Kull et al.

Kull et al teach a nucleic acid molecule comprising fragments of SEQ ID NO:1 of at least one nucleotide of SEQ ID NO:1, and thus also constituting a derivative of SEQ ID NO:1 or a sequence

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which would hybridize to SEQ ID NO:1 under conditions of at least low stringency, wherein said nucleic acid molecule was inserted into a vector in antisense orientation with respect to a promoter and introduced into potato plants, wherein said transformed potato plants produced tubers with altered starch composition (see, e.g., page 70; page 71, top paragraph of column 1 and Figure 1; page 72, column 2, penultimate paragraph; paragraph bridging pages 72 and 73). The reduction in cold-sweetening would have been an inherent property.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 73 and 92-93 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saint-Pierre et al.

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The claims are broadly drawn to propagation material from transformed potato plants, which material encompasses seed. Given the loss of single genes following Mendelian segregation during meiosis, and the failure of the claims to recite the retention of the transgene in the propagation material, the claims read on propagation material of wild-type potato.

Saint-Pierre et al teach potato plants and propagation material as stated above. The propagation material taught by the reference differs from the claimed material only in its method of production. However, the method of producing the claimed propagation material would not distinguish it from the propagation material taught by Saint-Pierre et al, as stated above. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claims 48-49, 51-57, 60-63, 65-69, 73-76, 81 and 88-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kull et al taken with Bird et al (U.S. Patent 6,013,861 effectively filed September 1992).

The claims are broadly drawn to potato plants transformed with an antisense construct to a glucan phosphorylase gene or "fragments" or "derivatives" thereof, and further exhibiting a reduction in another starch metabolism enzyme.

Kull et al teach potato plants transformed with an antisense construct to "fragments" or "derivatives" of a glucan phosphorylase gene, as stated above, but do not teach the use of another antisense construct corresponding to another starch metabolism gene.

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Bird et al suggest the inhibition of multiple starch synthesis enzymes for the production of starch with particular properties of interest, and suggest potato transformation (see, e.g., column 1, lines 15-21; column 3, lines 9 and 34-43 and 61-64; column 4, lines 59-63; columns 13-16).

It would have been obvious to one of ordinary skill in the art to utilize the method of altering starch fine structure via antisense transformation as taught by Kull et al, and to modify that method by incorporating additional antisense constructs corresponding to known starch synthesis genes, as suggested by Bird et al.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

June 15, 2002

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

